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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

BELGIUM

FROM 03 TO 14 SEPTEMBER 2012

IN ORDER TO EVALUATE THE OFFICIAL CONTROLS OVER THE PRODUCTION OF FARMED RABBIT MEAT, GELATINE AND RAW MATERIALS FOR GELATINE INTENDED FOR HUMAN CONSUMPTION

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

The objective of the audit was to evaluate the official controls over the production of farmed rabbit meat, gelatine and raw materials destined for the production of gelatine intended for human consumption.

The FAVV/AFSCA (the Federal Agency for the Safety of the Food Chain (the FAVV/AFSCA – Het Federaal Agentschap voor de Veiligheid van de Voedselketen/l'Agence Fédérale pour la sécurité de la Chaîne Alimentaire) is the competent authority (CA) responsible for the official controls over the production of farmed rabbit meat, gelatine and raw materials destined for the production of gelatine intended for human consumption. The organisation of the FAVV/AFSCA remains as described in the country profile Belgium.

Belgium has not laid down a procedure to verify the application of the requirements of Article 9 (1) of Directive No 92/65 EEC. Some consignments are accompanied by health certificates and reported in TRACES (trade control and expert system), others are traded with a commercial document only.

In general the official controls over the production of farmed rabbit meat is satisfactory. However some deficiencies were identified by the audit team of the Food and Veterinary Office (FVO) regarding the controls of the infrastructure, equipment and the slaughter hygiene. In one slaughterhouse visited, the FAVV/AFSCA had not evaluated the slaughter process of rabbits during the pre-approval inspection and during the routine control inspections. The traceability in this slaughterhouse was not guaranteed.

The FAVV/AFSCA controls in the rabbit holding visited did not reflect the poor hygiene conditions at the holding. The holding was only recently registered for this activity although it had provided rabbits for slaughter for several years.

Significant deficiencies were found in one tannery where some consignments were considered by the food and business operator (FBO) as suitable for human consumption although not accompanied by the appropriate trade documents. In addition the FBO accepted very dirty hides as raw material destined for the production of gelatine fit for human consumption. During the pre-tanning process a biocidal product was used which is prohibited in the European Union (EU). The FBO could not demonstrate that two other chemicals were authorised in the food and feed industry. The FVO audit team requested guarantees regarding this establishment.

In general the official controls over the processing of gelatine are satisfactory. The facilities of the tanneries which prepare raw material destined for the production of gelatine are not verified by the CA prior to authorisation. However, the official control over the storage of raw materials destined for the production of gelatine intended for human consumption was weak and many deficiencies were found.

The CA is in the process of, or has withdrawn after recent official controls, the authorisation of two out of three collection centres proposed to be visited by the FVO audit team for reasons on non-compliance with EU requirements. In addition a number of deficiencies were identified in the trade documents to accompany raw material destined for the production of gelatine intended for human consumption.

A number of recommendations have been made to the CA with a view to addressing the deficiencies identified during this audit.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation	
AFSCA	L'Agence Fédérale pour la sécurité de la Chaîne Alimentaire (the Federal Agency for the Safety of the Food Chain)	
CA	Competent Authority	
CCA	Central Competent Authority	
DG(SANCO)	Health & Consumers Directorate General	
EC	European Community	
EU	European Union	
FAVV	Het Federaal Agentschap voor de Veiligheid van de Voedselketen (the Federal Agency for the Safety of the Food Chain)	
FBO	Food Business Operator	
FVO	Food and Veterinary Office	
НАССР	Hazard Analysis and Critical Control Points	
RASFF	Rapid Alert System for Food and Feed	

1 Introduction

This audit took place in Belgium from 3 to 14 September 2012.

The audit was undertaken as part of the FVO's planned audit programme. The audit team comprised 2 auditors from the FVO.

The FVO audit team was accompanied throughout the audit by a representative of the Central Competent Authorities (CCA), the Federal Agency for the Safety of the Food Chain (the FAVV/AFSCA).

The opening meeting was held on 3 September 2012 with the CCA in Brussels. At this meeting the FVO audit team confirmed the objectives of, and itinerary for the audit, and additional information required for the satisfactory completion of the audit was requested.

2 OBJECTIVES

The objective of the audit was to evaluate the operation of official controls related to the production and storage of food of animal origin.

The FVO audit team reviewed in particular:

- the CA's organisation and operation; and
- the official controls over FBOs' compliance with general and specific rules on the hygiene of food of animal origin.

In particular, controls over farmed rabbit meat, gelatine and raw material for the production of gelatine intended for human consumption in the framework of Regulations (EC) No 178/2002, No 852/2004, No 853/2004, No 854/2004 and No 882/2004 were subject to this evaluation. In pursuit of these objectives, the audit itinerary included the following:

Competent Authority		Comments	
CA at Central level	1	The FAVV/AFSCA	
CA at regional and local level	1	3 regional offices, CA at local level was always present on site	
Food production/processing/distribution activities			
Slaughterhouses	3	2 exclusively for slaughtering of farmed rabbits; 1 combined with slaughtering of poultry	
Cutting plants	4	3 cutting plants were integrated in the slaughterhouses	
Cold store	1	Storage of imported consignments of rabbit meat	
Holding	1	Farmed rabbits	
Gelatine processing establishments	2		
Storage	1	Storage of raw material for gelatine intended for human consumption	

Tannery		Raw material for gelatine production intended for human consumption (hide splits)
Gelatine establishments	2	Processing final products from gelatine

3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation and, in particular Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

N.B. Full European Union (EU) legal references are provided in Annex 1. EU legal acts quoted in this report refer, where applicable, to the latest amended version.

4 BACKGROUND

4.1 Summary of previous FVO audit reports

4.1.1 Farmed rabbit meat

This was the first audit in Belgium regarding public health control systems in relation to official controls over the production of farmed rabbit meat.

In 2011, 2.948.091 rabbits were slaughtered in 12 approved slaughterhouses of which three slaughterhouses accounted for 95% of the animals slaughtered. The live rabbits originate from Belgium, five other Member States. In 2011, 4 223.6 tonnes of farmed rabbit meat were imported from China (source COMEXT).

One Border Rejection Notification was made through the Rapid Alert System for Food and Feed (RASFF) by the FAVV/AFSCA: Notification 2012.ASC - prohibited substance chloramphenicol in rabbit meat from China. All 19 tonnes of rabbit meat from this consignment from China imported into France via Belgium were destroyed in France.

4.1.2 Gelatine and raw materials destined for the production of gelatine intended for human consumption

A previous audit (reference DG (SANCO)/2007-7229) to evaluate the implementation of official controls for gelatine took place in Belgium in January 2007. The overall objective of the previous audit was to evaluate the measures put in place to give effect to rules concerning the sourcing and traceability of gelatine and the raw materials from which it is produced. The mission focused on the official controls implemented by the CAs in order to verify the correct sourcing, flow and destination of gelatine intended for human consumption and gelatine not intended for human consumption.

The report of the previous audit contained two recommendations with regard to the official controls on gelatine. One recommendation concerned the labelling requirements and the content of trade documents accompanying raw material destined for the production of gelatine. The second recommendation concerned the approval of gelatine processing plants. The action plan received from the FAVV/AFSCA provided satisfactory guarantees in response to both recommendations.

The FVO audit report mentioned is accessible at:

http://ec.europa.eu/food/fvo/index en.cfm

5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION

Legal requirements

Article 291.1 of the Treaty on the functioning of the EU requires that the Member States adopt all measures of national law necessary to implement legally binding Union acts.

Audit findings

The FAVV/AFSCA informed the FVO audit team that they had requested advice from the Scientific Committee on the use of surface water that does not fully comply with the requirements of Council Directive 98/83/EC for use as process water in the production of gelatine in the two gelatine processing establishments. The Committee's advice was positive with certain restrictions and gave a number of recommendations.

The FAVV/AFSCA had not officially formalised the derogations and the exemptions of the above water Directive due to the incomplete transposition of Council Directive 98/83/EC, in particular, Articles 3 and 9 respectively thereof into national legislation. The Committee's recommendations and restrictions for the use of surface water were not followed in particular in one establishment. In addition, Article 2.1(b) of the above water Directive limits this possibility to situations where the quality of water cannot affect the wholesomeness of the foodstuff in its finished form. Nevertheless, the process water was also used for cleaning the contact surfaces after production.

In one rabbit slaughterhouse visited, the nitrate concentration was often above the acceptable limit without the FBO being able to solve the problem permanently.

The FVO audit team was informed that new national legislation is being drafted concerning the welfare of rabbits at holdings. The draft Royal Decree is planned to enter into force on 1 January 2013¹, and contains transitional periods for its full implementation. The draft Royal Decree foresees that from 1 January 2025 all fattening and reproduction rabbits are to be kept in well defined parks and no longer in cages.

The Belgian authorities did not lay down additional requirements for the traceability of farmed rabbits at holding level or groups of animals from the same origin during transport².

The Belgian authorities have not laid down a procedure to verify the application of the requirements

¹ In their response to the Draft Report the Belgian CA noted that the draft Royal Decree is currently being examined by the Council of State. Publication is expected to occur in 2013.

² In their response to the Draft Report the Belgian CA noted that they do not intend to immediately adopt the measures for identifying live rabbits. Keepers of live rabbits are responsible for the traceability of their products. They will be reminded of the obligations concerning the traceability of rabbits referred to in Article 18(1) of Regulation (EC) No 178/2002.

of Article 9 (1) Directive No 92/65 EEC concerning the trade of farmed rabbits introduced from other Member States. Some consignments of farmed rabbits for slaughter from other Member States are accompanied by health certificates containing the animal health guarantees laid down in Articles 4 and 9 of Council Directive 92/65/EEC and are reported in TRACES (trade control and expert system), other consignments are accompanied by a commercial document only.

The food chain information accompanying the rabbits for slaughter was not always complete or signed (for more details see chapter 5.4.5)³.

The CA has notified the Commission of the "Draft Royal Decree on hygiene conditions relating to the direct supply of small quantities of certain foodstuffs of animal origin to the end consumer by an animal owner or other producer of primary products or hunter". It limits the maximum number of rabbits that may be slaughtered at the farm for direct sale to 500 or 1000 depending on the specific requirements.

Conclusion

The Belgian legislation does not provide the possibility for exemptions from the provisions of Council Directive 98/83/EC, Article 3 thereof. Nevertheless, the gelatine processing establishments use surface water which is not fully in line with the requirements of this Directive.

No national legislation has been established for either the identification of live rabbits or groups of rabbits from the same origin at holding level or/and when dispatched from their holding of origin. As a consequence farmed rabbits are sent and accepted for slaughter without being properly identified.

The FAVV/AFSCA did not guarantee that the animal health requirements lay down in Articles 4 and 9 of Council Directive 92/65/EEC are fully met for all consignments of rabbits sent for slaughter.

5.2 Competent Authorities

Legal requirements

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the CAs responsible for the purposes and official controls set out in the Regulation. It also lays down operational criteria for the CAs.

Article 8 of Regulation (EC) No 882/2004 requires that CAs carry out their official controls in accordance with documented procedures, containing information and instructions for staff performing official controls.

Audit Findings

³ In their response to the Draft Report the Belgian CA noted that the DGC memorandum CONT/2011/83 sets out the measures to be taken in the case of non-conformity in the FCI. The memorandum will shortly be amended as follows: If non-conformities are found concerning the relevant data regarding the FCI, the CDM (veterinarian head of mission) shall inform his/her PCU (provincial control unit) of this. The unit in question will investigate the person registered as being responsible for the abattoir for the animal in question and other persons concerned, if necessary. If the person responsible or the other persons are covered by another UPC, the UPC for the abattoir will refer the case to the other UPC in question.

The FAVV/AFSCA is the CA responsible for the official controls over the production of farmed rabbit meat, gelatine and raw materials destined for the production of gelatine intended for human consumption for gelatine. The country profile Belgium (Reference DG(SANCO)/2010/8369) describes arrangements for the implementation of certain requirements of Regulation (EC) No 882/2004 such as the designation of the CAs, resources for performance of controls, organisation and implementation of official controls, enforcement measures, verification and review of official controls and procedures, the Multi-Annual National Control Plan and the Annual Report. The country profile Belgium also describes the responsibilities of the CAs.

The FAVV/AFSCA have documented procedures for official controls. However the FAVV/AFSCA did not develop documented procedures for official controls at holdings where rabbits are kept. For the other type of establishments within the scope of this audit, documented procedures for official controls were in place.

The country profile Belgium is accessible at:

http://ec.europa.eu/food/fvo/country profiles en.cfm

5.2.1 Registration/approval of Food Business establishments

Legal requirements

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration/approval of food and feed business establishments, for reviewing compliance with conditions of approval and for the withdrawal of approvals.

Audit findings

The country profile Belgium describes that a system of registration and approval of establishments has been established in conformity with the requirements of Regulations (EC) No. 882/2004 (in particular Article 31), 852/2004 (in particular Article 6) and 853/2004 (in particular Article 4). The detailed rules for prior registration, authorisation and approval of establishments, and registration of FBOs are laid down in the Royal Decree of 16 January 2006 which assigns responsibility to the FAVV/AFSCA. The Royal Decree also regulates the renewal of all existing approvals. The authorisation procedure, which is applicable within the scope of this audit for tanneries and collection centres where raw materials destined for the production of gelatine intended for human consumption are stored, does not require a prior visit on the spot.

The procedure for registration/approval of food business establishments are in general followed as described in the country profile Belgium. However the following observations were made:

- One slaughterhouse was approved by the FAVV/AFSCA for slaughtering of poultry and farmed rabbits although the slaughter process specific for farmed rabbits has not been evaluated by the CA during the approval procedure or during the following supervisory visits.
- In one processing establishment for gelatine, the facilities for the storage of raw materials destined for the production of gelatine intended for human consumption were not compliant with the hygiene requirements. For more details see chapter 5.4.1.2.
- Another establishment was approved for storage and processing of raw materials for greaves
 whilst this activity was not carried out. The FAVV/AFSCA took immediate corrective action
 to amend the approval accordingly.

- With regard to the collection centres and tanneries, the FAVV/AFSCA did not verify if the FBO complies with the specific minimum requirements for the storage of raw materials destined for the production of gelatine intended for human consumption, as foreseen in Chapters I and II of Section XIV of Annex III to Regulation (EC) No 853/2004, prior to the authorisation of these types of establishments.
- The FVO audit team noted that a number of facilities for the storage of gelatine intended for human consumption at ambient temperature were only recently registered by the FAVV/AFSCA.

5.2.2 Prioritisation of official controls

Legal requirements

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. Controls shall be carried out at any of the stages of the production and processing chain and, in general, are to be carried out without prior warning. Controls shall be applied with the same care to exports from the EU, imports into the EU and to product placed on the EU market.

Audit findings

- In one slaughterhouse visited, the FAVV/AFSCA had not evaluated the slaughter process for farmed rabbits (see for more details chapter 5.2.1).
- Once authorised, the collection centres and tanneries are subject to a yearly minimum control frequency. The yearly frequency was not met for two establishments visited. This was also the case for one collection centre where the file has been evaluated by the FVO audit team. In two cases, the authorisation was withdrawn or suspended shortly before this FVO audit as a result of the official controls.
- The official controls in the other establishments visited were in line with the set frequency.
 - 5.2.3 Official sampling and laboratory analysis

Legal requirements

Article 10 of Regulation (EC) No 882/2004 laid down that tasks related to official controls shall, in general, be carried out using appropriate control methods and techniques. Sampling and analysis is one of the methods and techniques mentioned.

Audit findings

The FAVV/AFSCA tested in 2010 and 2011 samples of gelatine at different levels for the following microbiological parameters: *Bacillus cereus* and *Salmonella spp* respectively. None was found positive.

The FAVV/AFSCA tested in 2010 and 2011 samples of gelatine intended for human consumption for residues of Arsenic (As) only. None was found positive. The 2012 official sampling programme now includes all heavy metals mentioned in Chapter IV of Section XIV to Annex III to Regulation

(EC) No 853/2004, but does not include sulfurdioxide and hydrogen peroxide.

The FAVV/AFSCA presented the results of the tests on residues in farmed rabbit meat carried out in 2011 in the frame of the national residue monitoring programme. None of the 169 samples was found to be positive.

Conclusion

The organisation of the FAVV/AFSCA, the responsible CA for the organisation and implementation of official controls over the production of farmed rabbit meat, gelatine and raw materials destined for the production of gelatine intended for human consumption remains as described in the country profile Belgium.

The procedures for the approval and authorisation of establishments in place were followed by the FAVV/AFSCA. However the approval of one rabbit slaughterhouse was granted without having evaluated the slaughter process. For the collection centres/tanneries authorisation is granted by the FAVV/AFSCA at the request of the FBO but without prior verification of the special conditions. The official control system was not robust enough to identify non-compliances of a number of facilities for the storage of raw materials destined for the production of gelatine intended for human consumption. Only recent official controls identified significant non-compliances leading to the withdrawal or suspension of the authorisation of some establishments.

The recommendation of the previous report "to approve gelatine producing plants in accordance with the provisions laid down in Article 4(3) of Regulation (EC) No 853/2004" cannot be considered to have been satisfactorily addressed.

The FAVV/AFSCA had not developed documented procedures in place for official controls at holdings where farmed rabbits are kept.

5.3 HOLDING REGISTRATION, ANIMAL IDENTIFICATION, OFFICIAL CONTROLS OVER LIVE ANIMALS

Legal requirements

Council Directive 92/65/EEC, in particular Articles 4 and 9 thereof establishes the animal health conditions for trade of live rabbits. Live rabbits may only be traded if they come from holdings registered by the CA and the CA must ensure the implementation of the conditions of Article 4.

Article 3(3) of Council Directive 90/425/EEC sets out that the CA shall carry out checks on holdings in order to satisfy itself that animals intended for trade comply with EU requirements and, in particular, fulfil the conditions laid down in paragraphs 1(c) and (d) with regard to identification.

Audit findings

Holdings with more than 100 farmed rabbits for fattening and with more than 20 farmed rabbits for reproduction are registered in the database BOOD in accordance with the Royal Decree of 16 January 2006. The holdings are not registered in the national database (SANITEL) where other farmed animals such as bovine, porcine, ovine and caprine animals are registered.

The holding visited was only registered by the FAVV/AFSCA in February 2012 as a holding with rabbits. However live rabbits have been introduced from France to this holding for several years. Live rabbits were sent for slaughter to a nearby slaughterhouse regularly and the holding was

controlled for other farmed animals by the FAVV/AFSCA.

The FAVV/AFSCA did not identify during the official control at the holding visited the unhygienic circumstances (e.g. droppings were piled up under the cages, presence of old dust and dirt on the cages, walls with big gaps, insufficient protection against mosquitoes, storage of rodent pellets on top of the cages). There was no specific holding register kept containing the number of animals present, the number of births, number of dead animals and animals sent for slaughter. Poor records were kept on individual cages, which were not always readable. The keeper could not provide precise data on death rates.

Conclusion

One holding was only recently registered as a keeper of farmed rabbits although trade took place for several years. The FAVV/AFSCA did not guarantee that good hygiene practice was applied at the holding visited.

5.4 OFFICIAL CONTROLS OVER FOOD BUSINESS OPERATORS' COMPLIANCE WITH HYGIENE RULES AT

Legal requirements

Article 4(2) of Regulation (EC) No 852/2004 establishes that the FBO carrying out at any stage of production, processing and distribution of food after the stage of primary production/associated operations shall comply with general hygiene requirements as set out in Annex II to Regulation (EC) No 852/2004. These provisions relate to cleaning and maintenance, layout, design, construction, sitting and size of food premises. Regulation (EC) No 852/2004 does not apply to collection centres and tanneries as mentioned in Article 1.2(d) of this Regulation.

Article 3 of Regulation (EC) No 853/2004 sets out that the FBO shall comply with the specific requirements of Annexes II and III to this Regulation. Article 4(3) of Regulation (EC) No 852/2004 states that FBOs shall adopt specific hygiene measures regarding compliance with microbiological criteria for foodstuffs, compliance with temperature control requirements and sampling and analysis.

Article 4(2) of Regulation (EC) No 854/2004 specifies that the CA shall carry out official controls in respect of products of animal origin to verify the FBO's compliance with these requirements.

Audit findings

In one slaughterhouse visited, the FBO was not co-operative with the FVO audit team and with the FAVV/AFSCA on previous occasions. The traceability in this slaughterhouse was not guaranteed.

In this establishment no slaughtering of rabbits took place at the time of the FVO audit. Therefore the slaughter process could not be evaluated by the FVO audit team.

5.4.1 General and specific hygiene requirements

5.4.1.1 Farmed rabbit meat

In general the FBOs complied with the general and specific hygiene requirements. Nevertheless a few observations were made by the FVO audit team:

- Regarding the slaughter hygiene, deficiencies were seen in two establishments visited:
 - In one slaughterhouse visited, skinning and evisceration were not carried out in such a way that contamination of the meat was avoided. The equipment did not allow hygienic operation, in particular, the skinning and evisceration equipment⁴.
 - In another slaughterhouse visited insufficient measures were taken to prevent the spillage of digestive tract contents during evisceration.
 - In both establishments, the deficiencies regarding the slaughter hygiene noticed by the FVO audit team were caused due to a lack of training of the FBO staff, their supervision and corrective measures⁵.
- Regarding the operational hygiene observations were made in three establishments visited:
 - In one establishment despite controls at the point of reception of the carcasses, some contaminated carcasses entered the automatic cutting process.
 - In one establishment the storage of packing material was not acceptable. Some mouldy cartons were stored in a corridor (former cold store) where condensation was present⁶.
 - In one establishment, cross-contamination could occur in one chiller due to the presence of packed and unpacked meat, wooden pallets, meat products and cheese.
- Deficiencies regarding the structure and equipment were seen:
 - The killing of the rabbits in two slaughterhouses visited was not separated from the reception area for live animals.
 - The lack of containment of waste water, the construction of the automatic evisceration machine, the lack of sufficient hand wash basins at certain work stations caused some cross-contamination⁷.

⁴ In their response to the Draft Report the Belgian CA noted that this has been drawn to the attention of the slaughterhouse and the operator has responded in its action plan: review of the slaughtering process with adjustments where necessary.

⁵ In their response to the Draft Report the Belgian CA noted that additional measures have been taken regarding the lack of training for staff and also supervision.

⁶ In their response to the Draft Report the Belgian CA noted that all the mouldy packaging material was destroyed. Cooling switched off at the premises, eliminating condensation.

⁷ In their response to the Draft Report the Belgian CA noted that because of the recent refurbishment of the unclean part of the slaughterhouse, there is still a lack of appropriately positioned washing basins: this will be rectified as soon as possible. The sprinklers of the evisceration machine are now aimed more effectively, avoiding cross-contamination.

- In one establishment visited, the cleaning and disinfection of crates for live rabbits was insufficient⁸.
- Most of the deficiencies identified by the FVO audit team were not noted during the official controls.
 - 5.4.1.2 Gelatine and raw materials destined for the production of gelatine intended for human consumption

5.4.1.2.1 Transport and storage of raw materials

The consignments of raw materials destined for the production of gelatine for human consumption were in general accompanied by a trade document, following the model laid down in Regulation (EC) No 853/2004. However a number of observations were made by the FVO audit team:

- Nearly all trade documents which have been verified by the FVO audit team contained an additional attestation regarding the origin of the hides and skins. In particular it was attested by the FBOs that the raw materials derived from healthy animals that had undergone antemortem and post-mortem inspection were found fit for human consumption. The FBOs request this statement for their clients or in view of future certification.
- In one establishment, a number of trade documents did not specify that the raw materials destined for the production of gelatine was intended for human consumption.
- In the establishments visited, a number of trade documents were not completed correctly regarding the origin and provenance, in particular, when the consignments were traded through collection centres and/or storage facilities.
- In one establishment a series of deficiencies were identified regarding the trade document accompanying raw material destined for the production of gelatine intended for human consumption:
 - Some trade documents accompanying consignments of hides referred to the obsolete Council Directive 92/118/EEC;
 - Some consignments of hides were accompanied by trade documents indicating the raw materials were destined for the production of gelatine intended for human consumption as well as with trade documents for category 3 materials (thus not intended for human consumption);
 - Some consignments of hides were accompanied by trade documents for category 3 materials only, whilst the hides were considered fit for human consumption by the FBO;
 - For one consignment of hide splits dispatched to a gelatine processing plant, the trade document indicated that the raw material is destined for the production of gelatine intended for human consumption. The transport document however, stated that it concerned category 1 high risk materials.

The FVO audit team requested the FAVV/AFSCA to take corrective action in relation to consignments where it could not be ascertained that raw materials for gelatine for human consumption were fit for or intended for human consumption.

• In one establishment the following observations were made regarding the storage of raw materials destined for the production of gelatine intended for human consumption:

⁸ In their response to the Draft Report the Belgian CA noted that the manufacturer has been contacted to supply the system characteristics of the new crate washing machine for cleaning and disinfection.

- Fresh pig skins were not stored chilled and the FBO could not guarantee that the skins are processed within the legal limit of 24 hours. The FAVV/AFSCA confirmed that the FBO plans to install chilling facilities. In the storage facilities two consignments were present, which were not properly packed and which were partially contaminated with dirt. Part of the consignments was in contact with the wall on which algae were growing.
- o In addition pieces of fresh pig skins collected during the cleaning of the trucks (i.e. from the floors) following delivery, were stored in an open crate outside, unprotected and contaminated with dirt. The FBO stated that this raw material will still be used for the production of gelatine for human consumption.
- In another area where dehydrolysed pig bones were stored at ambient temperature the walls, ceiling and floors were not smooth and easy to clean. In addition the walls and ceiling were very dirty and contained dust¹⁰.

The official control reports did not reflect the above observations made by the FVO audit team regarding the trade and eligibility of raw materials destined for the production of gelatine intended for human consumption. The FAVV/AFSCA did not identify the deficiencies made regarding the debris from cleaning trucks and the non-compliant facilities for the storage of the dehydrolysed pig bones.

5.4.1.2.2 Processing of gelatine

Pre-tanning process

One tannery visited produced hide splits destined for the production of gelatine intended for human consumption. A number of observations were made by the FVO audit team:

- The lay-out of the tannery did not allow a continuous flow of the production process.
- Part of the facilities, in particular where the production of hide splits took place were not clean. In this part weeds were growing inside the building.
- Not all of the equipment for the pre-tanning process was of a non-corrosive material. The tables where hides were scraped of fat and muscular meat consisted of wood with a PVC working surface. The working surface was not smooth. Paint was flaking off the equipment where hides were split.
- The FBO stated that the equipment, including the containers to store the hide splits was cleaned with water only.
- The FVO audit team identified that extremely dirty skins have been declared by the consignor as being fit for human consumption and accepted by the FBO for the production of hide splits. The FBO did not have criteria for refusal or acceptance of dirty skins for food production purposes.
- The FAVV/AFSCA authorised the tannery at the end of 2008 for the storage of raw materials destined for the production of gelatine intended for human consumption. The FBO stated that only from January 2012 were hide splits produced for the production of gelatine intended for human consumption. The first official control by the FAVV/AFSCA since its authorisation took place in June 2012. During this control the FAVV/AFSCA identified that during the pre-tanning process certain products were used such as a biocide (Busan 85 ® containing potassium dimethyldithiocarbamate) and other alcohol-derivatives for which the

⁹ In their response to the Draft Report the Belgian CA noted that a cooling system has now been placed in service.

¹⁰ In their response to the Draft Report the Belgian CA noted that it is necessary to take account of the nature of the product when considering the requirements for the infrastructure.

FBO could not demonstrate that these were safe for use in the food industry. As a safeguard measure (in addition to more specific findings related to animal by-products), the FAVV/AFSCA suspended the special authorisation of the tannery. The active substance Potassium dimethyldithiocarbamate cannot be used in the EU as a type 20 biocidal product. Consequently in line with the provisions of Directive 98/8/EC on biocidal products, Busan 85 ® cannot be placed on the EU market to come into contact with foodstuffs.¹¹

Processing of gelatine

The FBO informed the FVO audit team that gelatine is produced only from porcine bones and pig skins. The bovine bones are used for the production of ossein. The use of bovine skins for the production of gelatine for human consumption stopped shortly before the start of this audit. The bovine bones mainly originate from India. The porcine bones, bovine hides and pig skins are of Belgian origin and other Member States. Bovine hides are also sourced from Norway.

In general the processing of gelatine was satisfactory and in line with the legal requirements.

5.4.2 HACCP-based systems

Legal requirements

On the basis of Article 5 of Regulation (EC) No 852/2004 the FBO shall put in place, implement and maintain a permanent procedure or procedures based on the Hazard Analysis Critical Control Point (HACCP) principles. Official controls in respect of all products of animal origin in the scope of Regulation (EC) No 854/2004 shall include audits of HACCP-based producers (Article 4.3(a) and (5) of Regulation (EC) No 854/2004).

Audit findings

5.4.2.1 Farmed rabbit meat

The farmed rabbit meat processing establishments visited had HACCP based systems in place. The verification is included in the official controls and was carried out as programmed. No major deficiencies were identified by the FVO audit team and during the official controls by the FAVV/AFSCA. However, in one establishment positive results on *E. coli* were not investigated and no corrective action followed (see also chapter 5.4.3.1).

5.4.2.2 Gelatine

The gelatine processing establishments visited had HACCP based systems in place. In addition to the required testing for residues of parameters specified in Regulation (EC) No 853/2004 more parameters were tested, and the FBOs established for some parameters stricter norms than legally requested.

The FAVV/AFSCA failed to identify that the FBO did not investigate the source of contamination of consignments of gelatine of which the FBO obtained positive results for coliform bacteriae (see also chapter 5.4.3.2).

Results of tests for residues of finished products as specified in Chapter IV of Section XIV of Annex III to Regulation (EC) No 853/2004 were available. At one gelatine processing establishment

¹¹ In their response to the Draft Report the Belgian CA noted their insistence that all companies of this type observe the same requirements concerning biocidal products throughout the EU, to avoid unfair competition.

visited, the FVO audit team noted that the FBO as part of their own checks tested the parameters in a pooled sample of a weekly production. Although the legislation does not imposes any sampling frequency, it is not considered as a good practice and reduces the reliability of the monitoring.

5.4.3 Microbiological criteria for foodstuffs

Legal requirements

Details on the microbiological criteria foodstuffs shall comply with are set out in Regulation (EC) No 2073/2005. Article 1 of Regulation (EC) No 2073/2005 specifies that the CA shall verify compliance with the rules and criteria laid down in that Regulation.

Audit findings

5.4.3.1 Farmed rabbit meat

Regulation (EC) No 2073/2005 does not establish microbiological criteria for farmed rabbit meat. In two establishments visited, the FBO carried out microbiological carcass sampling of carcasses for coliform bacteriae and *Salmonella*. In one establishment positive results on *E. coli* were not investigated and no corrective action followed.

5.4.3.2 Gelatine and raw materials destined for the production of gelatine intended for human consumption

Results of tests of gelatine for *Salmonella* were available. The FBOs stated they had set more microbiological parameters based on a recommendation made by the Gelatine Manufacturers of Europe. Tests are also carried out for coliform bacteriae, *Clostridium*, yield and mould and total bacterial count. In one establishment visited, positive results were found for coliform bacteriae but there was no follow-up of the origin of the contamination.

5.4.4 Traceability, labelling and identification marking

Legal requirements

According to Article 18 of Regulation (EC) No 178/2002 the traceability of food and food-producing animals and any other substance intended to be incorporated into a food shall be established at all stages of production, processing and distribution. The FBO shall have in place systems and procedures to identify from whom they have been supplied and the other businesses to which their products have been supplied. Article 4(6) of Regulation (EC) No 854/2004 requires that the verification of compliance with traceability requirements takes place in all approved establishments.

Provisions for the identification marking of a product of animal origin are made in Article 5 and Annex II, Section I to Regulation (EC) No 853/2004 and verification of compliance with these requirements is foreseen by Article 4(6) of Regulation (EC) No 854/2004. Article 3 of Directive 2000/13/EC sets out the particulars on the labelling of foodstuffs to be delivered as such to the ultimate consumer. Chapter V of section XIV of Annex III to Regulation (EC) No 853/2004 sets out labelling requirements for gelatine fit for human consumption (finished products).

Audit findings

5.4.4.1 Farmed rabbit meat

All establishments visited had traceability systems in place and the identification marking was carried out in a satisfactory manner. However in one establishment visited the traceability of rabbit meat could not be guaranteed. The FBO could not demonstrate for a number of consignments of farmed rabbits slaughtered where the rabbit meat has been dispatched to. For a number of consignments of rabbit meat dispatched from the slaughterhouse visited, the FBO could not demonstrate the trace back to the origin. In addition the labels on the trays and package material present in the cold store indicated the use-by-date, which was according to the FBO the actual production date.

The FAVV/AFSCA explained in a satisfactory manner the follow-up of the RASFF Border Rejection Notification 2012.ASC regarding the positive results on residues of the prohibited substance chloramphenicol in rabbit meat from China.

5.4.4.2 *Gelatine*

All establishments visited had traceability systems in place, the gelatine intended for human consumption was correctly labelled and foreseen with identification marks.

5.4.5 Food Chain information

Legal requirements

According to Article 3 of Regulation (EC) No 853/2004, the FBO shall comply with the relevant provisions of Annex II and III to this Regulation. In particular the FBOs operating slaughterhouses must as appropriate, request, receive, check and act upon food chain information in respect of all animals, other than wild game, sent or intended to be sent to the slaughterhouse. According to Article 5(1) of Regulation (EC) No 854/2004 the official veterinarian shall carry out inspection tasks in slaughterhouses also as regards the food chain information.

Audit findings

The FAVV/AFSCA had established a model for the food chain information for farmed rabbits sent to slaughter. The model is enforced since 1 January 2012. It contains no statements to be signed by the keeper of the holding of origin, including those on the absence of symptoms of myxomatose or the absence of rabies or no contact with outbreaks or suspect cases of rabies within the last month. ¹²

The food chain information was available for the consignments verified by the FVO audit team in the three slaughterhouses visited. The content of the models from other Member States were not following a uniform approach and did not always include the animal health statements as required by Council Directive 92/65/EEC. Several documents containing the food chain information were not completed or signed by the previous keeper of the farmed rabbits. The FBO and the FAVV/AFSCA could not demonstrate that action had been taken in those cases.

5.4.6 Ante-mortem and post-mortem inspection

Legal requirements

¹² In their response to the Draft Report the Belgian CA noted that it is necessary to determine whether such a declaration is still necessary, either in a separate document or in the FCI transmission document.

Article 5(1) of Regulation (EC) No 854/2004 requires that the official veterinarian carries out inspection tasks, including ante-mortem inspection of all animals before slaughter in accordance with the general requirements of Section I, Chapter II of Annex I to Regulation (EC) No 854/2004 and post-mortem inspection in accordance with the general requirements of Section I, Chapter II of Annex I and the specific requirements of Section IV, Chapter VI of Annex I to Regulation (EC) No 854/2004.

Audit findings

Live rabbits or the group of animals from the same origin sent for slaughter were not identified. The loading plan of the truck and the dedicated storage in the unloading area of the slaughterhouse are not conclusive as similar cages are used and rabbits from different batches could also not be distinguished.

The FAVV/AFSCA informed the FVO audit team that ante-mortem inspection takes place at the slaughterhouses prior to slaughter and not at the holding of origin. Results of the ante-mortem inspection are well documented.

The post-mortem inspection is done solely by veterinarians on the line. However, due to the organisation of the work, in combining ante- and post-mortem inspection, post-mortem inspection of all animals is not ensured. In addition, in one slaughterhouse visited with the high speed of the slaughter line, the official veterinarian concentrated on the carcasses only.

5.4.7 Animal welfare at the time of slaughter or killing

Legal requirements

Article 5(1) of Regulation (EC) No 854/2004 requires that the official veterinarian carries out inspection tasks, including animal welfare. Council Directive 93/119/EC sets out EU rules with regard to the protection of animals at the time of slaughter or killing.

Audit findings

The FBOs of the three slaughterhouses visited were insufficiently aware of the changes to the animal welfare legislation laid down in Council Regulation (EC) No 1099/2009, that comes into force from January 2013. The FAVV/AFSCA stated they had informed the Slaughter Associations in Belgium about the changes, in particular concerning the obligation to designate an animal welfare officer and to provide appropriate training to the officers involved with the handling of live animals at slaughterhouses¹³.

The equipment in one slaughterhouse visited was not yet fitted with the audible or visible device and a device indicating the voltage and the current under load was not clearly visible to the operators. This only required from 1/1/2013.

5.4.8 Documentation of official controls

Legal requirements

13 In their response to the Draft Report the Belgian CA noted that the letter was sent to the sector by the CA on 6 July 2012.

Article 9 of Regulation (EC) No 882/2004 requires CAs to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned.

Audit findings

A reporting system is in place as described in the country profile Belgium. The results of official controls are well documented and were available in the establishments visited with one exception.

However, several deficiencies were not mentioned or adequately followed-up. In a few cases seen, deficiencies which scored a lower weight, not leading to unfavourable results were repeated in some subsequent reports. The FVO audit team noticed also that a number of questions mentioned in the report were not evaluated in depth, in particular the trade documents accompanying consignments of raw materials destined for the production of gelatine intended for human consumption.

Conclusion

Farmed rabbit meat

In general the FAVV/AFSCA has control over the production of rabbit meat. However a number of deficiencies were identified by the FVO audit team, in particular:

- the non-compliance of the FBOs regarding the slaughter hygiene in order to avoid contamination of the farmed rabbit meat during skinning and evisceration. In one establishment this was partly caused by the equipment in use;
- the absence of proper identification of rabbits (or group of rabbits) sent for slaughter;
- regarding the infrastructure of slaughterhouses, the absence of separation between the killing and reception areas;
- the lack of corrective action by the FBO when monitoring of the FBO indicates that a microbiological parameter is not under control; and
- the non-compliant stunning equipment for farmed rabbits in one slaughterhouse visited.

Gelatine and raw materials destined for the production of gelatine intended for human consumption

In general the FAVV/AFSCA has control over the production process of gelatine intended for human consumption, however the control over the facilities approved or authorised to store raw materials destined for the production of gelatine for human consumption was weak.

The minimum frequency of official controls of authorised establishments for the storage of raw materials destined for the production of gelatine intended for human consumption was not met. With one exception, the facilities visited did not comply with the requirements for the storage of the raw materials destined for the production of gelatine intended for human consumption.

The FAVV/AFSCA took safeguard measures in one tannery visited, however, only after a recent visit. At this establishment the FBO and the FAVV/AFSCA could not guarantee that certain products used in the production process are safe for use in food and feed. In addition the FBO used

one biocide that is not authorised for use in the EU as a biocidal product. In addition the lay out of the production process, the equipment in place and the acceptance of very dirty hides did not allow good hygienic practice¹⁴.

The FAVV/AFSCA addressed only part of the recommendation of the previous report (related to labelling and trade documents) whereas the content of the commercial documents accompanying raw materials destined for the production of gelatine was not satisfactorily addressed.

Deficiencies were identified in the FAVV/AFSCA controls over the FBOs' HACCP programmes in place, in particular regarding the follow-up to positive test results for microbiological parameters.

6 Overall Conclusions

In general the official controls over the production of farmed rabbit meat is satisfactory. However some deficiencies were identified by the FVO audit team regarding the controls of infrastructure, equipment and the slaughter hygiene. In one slaughterhouse visited, the FAVV/AFSCA had not evaluated the slaughter process of rabbits during the pre-approval inspection and during the routine control inspections. The traceability in this slaughterhouse was not guaranteed.

The FAVV/AFSCA controls in the rabbit holding visited did not reflect the poor hygiene conditions at the holding. The holding was only recently registered for this activity although it had provided rabbits for slaughter for several years.

Significant deficiencies were found in one tannery where some consignments were considered by the FBO as suitable for human consumption although not accompanied by the appropriate trade documents. In addition the FBO accepted very dirty hides as raw material destined for the production of gelatine fit for human consumption¹⁵. During the pre-tanning process a biocidal product was used which is prohibited in the EU. The FBO could not demonstrate that two other chemicals were authorised in the food and feed industry. The FVO audit team requested guarantees regarding this establishment.

In general the official controls over the processing of gelatine are satisfactory. The facilities of collection centres and tanneries who prepare raw material destined for the production of gelatine are not verified by the CA prior to authorisation. However, the official control over the storage of raw materials destined for the production of gelatine intended for human consumption was weak and many deficiencies were found.

The CA is in the process of, or has withdrawn, after recent official controls the authorisation of two out of three collection centres/tanneries proposed to be visited by the FVO audit team for reasons of non-compliance with EU requirements. In addition a number of deficiencies were identified in the trade documents to accompany raw material destined for the production of gelatine intended for human consumption.

¹⁴ In their response to the Draft Report the Belgian CA noted that it is necessary to take into account the type of undertaking and the type of raw materials being handled.

¹⁵ In their response to the Draft Report the Belgian CA noted that they had contacted the Irish authorities to inform them that the very dirty bovine hides were sent to a tannery that used them as raw materials for the production of gelatine for human consumption. They inspected the supplier of hides and required it to cease declaring that the skins were fit for human consumption.

7 CLOSING MEETING

A closing meeting was held on 14 September 2012 with the CCA, the FAVV/AFSCA. At this meeting the FVO audit team presented the findings and preliminary conclusions of the audit and advised the CCA of the relevant time limits for production of the report and their response.

The representative of the CCA took note of the findings and conclusions presented by the FVO audit team. At the closing meeting, the CA pointed out that it is difficult for establishments stocking bovine hides to have an exact idea of reasonable requirements concerning infrastructure hygiene (references to point 5 of chapter I of section XIV of Regulation (EC) No 853/2004), in view of the nature of the raw materials and their cleanliness, which is completely relative.

The FVO audit team requested the CCA to review the approval of one rabbit slaughterhouse visited in particular and to take corrective measures if needed.

8 RECOMMENDATIONS

An action plan, describing the action(s) taken or planned in response to the recommendations of this report and setting out a timetable to correct the deficiencies found, should be presented to the Commission within 25 working days of receipt of the report.

N°.	Recommendation
1.	To ensure that the requirements of Council Directive 98/83/EC are met, in particular when surface water is used in food production facilities.
2.	To ensure that live rabbits (or groups of rabbits from a same holding of origin) are accepted for slaughter only if properly identified, in line with the requirements of Chapter III of Section II of Annex I to Council Regulation (EC) No 854/2004.
3.	To review the documented procedures for official controls at holdings where rabbits are kept, in line with Article 8 of Regulation (EC) No 882/2004 in order to enable the official veterinarians to verify the relevant requirements on animal identification, registration, movement, good hygienic practice and animal welfare conditions.
4.	To ensure that the approved rabbit slaughterhouses meet the relevant requirements laid down in Annex III to Regulation (EC) No 853/2004. Particular attention should be given to the stunning and killing areas, animal welfare equipment and slaughter hygiene.
5.	To review the procedures for the authorisation of collection centres and tanneries in order to ensure the conditions are met for the storage of raw material destined for the production of gelatine intended for human consumption in line with the requirements laid down in Article 31 of Regulation (EC) No 882/2004.
6.	To review the authorisation of all collection centres and tanneries and the approval of processing establishments where raw materials destined for the production of gelatine

N°.	Recommendation
	intended for human consumption are stored in order to ensure that the conditions are met for storage of these raw materials as laid down in point 5 of Chapter I and point 2 of Chapter II of Section XIV of Annex III to Regulation (EC) No 853/2004.
7.	To ensure that the raw materials destined for the production of gelatine intended for human consumption during transport to a collection centre or tannery and when delivered to the gelatine processing establishments are accompanied by the trade document containing the information set out in point 1 of Chapter II of Section XIV of Annex III to Regulation (EC) No 853/2004.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6353

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	p. 1, Corrected and	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	p. 55, Corrected and	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 854/2004	p. 206, Corrected and	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 882/2004		Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs

Legal Reference	Official Journal	Title	
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004	
Reg. 1099/2009	OJ L 303, 18.11.2009, p. 1-30	Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing	
Reg. 1162/2009	OJ L 314, 1.12.2009, p. 10–12	Commission Regulation (EC) No 1162/2009 of 30 November 2009 laying down transitional measures for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council	
Dir. 90/425/EEC	OJ L 224, 18.8.1990, p. 29-41	Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market	
Dir. 92/65/EEC	OJ L 268, 14.9.1992, p. 54-72	Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC	

Legal Reference	Official Journal	Title
Dir. 92/118/EEC	OJ L 62, 15.3.1993, p. 49-68	Council Directive 92/118/EEC of 17 December 1992 laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC
Dir. 93/119/EC	OJ L 340, 31.12.1993, p. 21-34	Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing
Dir. 96/22/EC	OJ L 125, 23.5.1996, p. 3-9	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of \(\beta\)-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dir. 98/8/EC	OJ L 123, 24.4.1998, p. 1-63	Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market
Dir. 98/83/EC	OJ L 330, 5.12.1998, p. 32-54	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption
Dir. 2000/13/EC	OJ L 109, 6.5.2000, p. 29-42	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs